



Safety Data Sheet

Antibiotic Bone Cement Liquid

Printing date 10/05/2016

Version No.1

Reviewed on 10/05/2016

1. Identification

- **Product identifier**
- **Trade name:** [NTCem, NTCem-Violet, NTCem-Yellow, NTCem-Mixer] Liquid
- **Relevant identified uses of the substance or mixture and uses advised against:**
No further relevant information available.
- **Application of the substance / the mixture:** Antibiotic Bone cement Liquid
- **Manufacturer/Supplier:**
META BIOMED CO., LTD.
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Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel : +82-43-218-1981 / Fax : +82-43-218-1984
- **Information department:** alex@meta-biomed.com
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Meta Biomed US Corporation : +1-267-282-5893

2. Hazards identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapor.
Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
STOT SE 3 H335 May cause respiratory irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Harmful:
Harmful by inhalation, in contact with skin and if swallowed.

- **Irritant:**
Irritating to respiratory system and skin. May cause sensitisation by skin contact.

- **Highly flammable:**
Highly flammable.

- **Danger of cumulative effects.**
- **Information concerning particular hazards for human and environment:**
The product has to be labeled due to the calculation procedure of international guidelines.
- **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS02



GHS07

- **Signal word:** Danger

- **Hazard-determining components of labeling:** methyl methacrylate

- **Hazard statements:**

Highly flammable liquid and vapor.

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

- **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

Take precautionary measures against static discharge.

In case of fire: Use for extinction: CO2, sand, extinguishing powder.

Store in a well-ventilated place.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 2

Fire = 3

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 2

Fire = 3

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.



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3. Composition/information on ingredients

· Chemical characterization: Mixtures		
· Dangerous components:		
80-62-6	methyl methacrylate	50-100%
99-97-8	N,N-dimethyl-p-toluidine	< 5.0%

4. First aids measures

· Description of first aid measures
· General information: In case of accident or if you feel unwell, seek medical advice immediately.
· After inhalation: Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
· After swallowing: Rinse mouth with water. Do not induce vomiting; immediately call for medical help.
· Information for doctor:
· Most important symptoms and effects, both acute and delayed: No further relevant information available.
· Indication of any immediate medical attention and special treatment needed : No further relevant information available.

5. Fire fighting measures

· Extinguishing media
· Suitable extinguishing agents: CO ₂ , sand, extinguishing powder. Do not use water.
· Special hazards arising from the substance or mixture: Can form explosive gas-air mixtures. Formation of toxic gases is possible during heating or in case of fire.
· Advice for firefighters
· Protective equipment: Mouth respiratory protective device.
· Additional information -

6. Accidental release measures

· Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
· Environmental precautions: Prevent seepage into sewage system, workpits and cellars.
· Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Do not flush with water or aqueous cleansing agents Send for recovery or disposal in suitable receptacles.
· Reference to other sections See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

7. Handling and storage

- **Handling:**
- **Precautions for safe handling:**
 - Wear protective equipment. Keep unprotected persons away.
 - Keep receptacles tightly sealed.
 - Ensure good ventilation/exhaustion at the workplace.
- **Information about protection against explosions and fires:**
 - Keep ignition sources away - Do not smoke. Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8. Exposure controls/personal protection

- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate (50-100%)

PEL	Long-term value: 410 mg/m ³ , 100 ppm
REL	Long-term value: 410 mg/m ³ , 100 ppm
TLV	Short-term value: 410 mg/m ³ , 100 ppm Long-term value: 205 mg/m ³ , 50 ppm (SEN) NIC-DSEN, RSEN

99-97-8 N,N-dimethyl-p-toluidine (< 5.0%)

WEEL	Long-term value: 0.5 ppm
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- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
- **Breathing equipment:** Not necessary if room is well-ventilated.
- **Protection of hands:**



Protective gloves

Check protective gloves prior to each use for their proper condition.



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· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· For the permanent contact gloves made of the following materials are suitable:

For example:

Glove system consisting of two superimposed wearing gloves:
inner glove made of latex, outer glove made of polyethylene

· Eye protection: Safety glasses

· Body protection: Light weight protective clothing

9. Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Fluid

Color: Green

· Odor: Characteristic

· Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: -48 °C (-54 °F)

Boiling point/Boiling range: 101 °C (214 °F)

· Flash point: 10 °C (50 °F)

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: 430 °C (806 °F)

· Decomposition temperature: Not determined.

· Auto igniting: Not determined.

· Danger of explosion: Not determined.

· Explosion limits:

Lower: 2.1 Vol %

Upper: 12.5 Vol %

· Vapor pressure at 20 °C (68 °F): 47 hPa (35 mm Hg)

· Density at 20 °C (68 °F): 0.94 g/cm³ (7.844 lbs/gal)

· Relative density Not determined.

· Vapour density Not determined.

· Evaporation rate Not determined.

· Solubility in / Miscibility with Water at 20 °C (68 °F): 1.6 g/l

· Partition coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

· Solvent content:

Organic solvents: 0.0 %

· Other information:

No further relevant information available.

10. Stability and reactivity

· Reactivity

· Chemical stability

· Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.



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- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11. Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

80-62-6 methyl methacrylate

Oral	LD50	7872 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rabbit)
Inhalative	LC50/4 h	29.8 mg/l (rat)

99-97-8 N,N-dimethyl-p-toluidine

Oral	LD50	500 mg/kg (rat)
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- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

80-62-6	Methyl methacrylate	3
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

12. Ecological information

- **Toxicity**

- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

- **Additional ecological information:**

- **General notes:** Avoid transfer into the environment.

- **Results of PBT and vPvB assessment**



- **PBT:** Not applicable.
- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13. Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14. Transport information

- | | |
|---|---|
| <ul style="list-style-type: none"> · UN-Number · DOT, ADR, IMDG, IATA: UN1247 <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · UN proper shipping name · DOT, ADR, IMDG, IATA: Void <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · Transport hazard class(es) · DOT <div style="text-align: center;">  </div> <ul style="list-style-type: none"> · Class: 3 Flammable liquids. · Label: 3 <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · ADR, IMDG, IATA <div style="text-align: center;">  </div> <ul style="list-style-type: none"> · Class: 3 Flammable liquids · Label: 3 | <ul style="list-style-type: none"> · Packing group · DOT, ADR, IMDG, IATA: II <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · Environmental hazards: · Marine pollutant: No <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · Special precautions for user:
Warning: Flammable liquids · Danger code (Kemler): 339 · EMS Number: F-E,S-D <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable <hr style="border-top: 1px dashed black;"/> <ul style="list-style-type: none"> · UN "Model Regulation":
UN1247, Methyl methacrylate monomer, stabilized, solution, 3,II |
|---|---|

15. Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

· Section 355 (extremely hazardous substances):
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None of the ingredient is listed.

· Section 313 (Specific toxic chemical listings):
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80-62-6 methyl methacrylate

· **TSCA (Toxic Substances Control Act):**

Medical devices are exempted from TSCA.

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

80-62-6

methyl methacrylate

E, NL

· **TLV (Threshold Limit Value established by ACGIH)**

80-62-6

methyl methacrylate

A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS02

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**

methyl methacrylate

· **Hazard statements**

Highly flammable liquid and vapor.

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.



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· **Precautionary statements**

- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Take precautionary measures against static discharge.
- In case of fire: Use for extinction: CO2, sand, extinguishing powder.
- Store in a well-ventilated place.

· **National regulations:**

Class	Share in %
I	2.0

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** HH-EHS-CS

- **Date of preparation / last revision:** 10/05/2016 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3